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| 09/777,920 | 02/07/2001 | Jacques Dumas | BAYER 15 P3 | 6183 |

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EXAMINER

DESAI, RITA J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1625

DATE MAILED: 01/15/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/777,920

Applicant(s)

Jacques DUMAS et al

Examiner

RITA J. DESAI

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other: _____

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 31-33 and 1-30 in part, drawn to compounds, pharmaceutical compositions and method of treating wherein the compounds B is a quinoline, isoquinolinyll or a pyridyl moiety, A is a group wherein q is 1, M is O, L is a phenyl and L' is a phenyl or a 5 or 6 membered hetero ring containing Nitrogen only, classified in class 546, 514 subclass 152, 180, 277.4, 277, 311, 312-314.
- II. Claim 1-30 in part drawn to compounds, compositions and method of using these compounds wherein A and B are different than in group I, classified in various classes and subclasses. Subject to further restriction. A further election of a single disclosed species is required.

The inventions are distinct, each from the other because of the following reasons:

The different A and B substituents have so many variables with the heterocyclic and non-hetero groupings, they have different bonding and properties, and have achieved a different status in the art, and is burdensome to search and hence are objected to as being drawn to an improper Markush group on the grounds of lack of a common nucleus. The terms Rx, Ry, Rz along with A and B, are so broad in scope that a prior art reference anticipating the claims with respect to one member under 35 USC 102(b) would not render obvious the same claims under 35 USC 103a with respect to another member. The improper Markush group rejection finds basis in case law, compare *In re Swenson* 56 USPQ 180; *In re Ruzicka*, 66 USPQ 226; *In re Winnek*, 73 USPQ 225; *In re Harnisch*, 206 USPQ 300, 305 (CCPA 1980). In view of the foregoing, restriction is required to the following inventions under 35 USC 121.

If applicants traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr Traverso on 12/21/2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 31-33 and 1-30 in part. Affirmation of this election must be made by applicant in replying to this Office action. Claim 1-30 in part are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants are required to cancel all the non elected subject matter in their response. Applicants preserve their right to file a divisional on the canceled non-elected subject matter without prejudice in due course.

Claim Objections

Claims 31-33 are objected to because of the following informalities: The claims have figures pasted on it. The figures of the chemical compounds are not printed in the claim. Applicant is required to submit amended claims with appropriate the appropriate correction.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

SCOPE OF ENABLEMENT

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Rx, Rz, Rf to be a lower alkyl, does not

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reasonably provide enablement for any hetero or other large group of 1-30 or 1-40 carbon atoms with other hetero atoms.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The guidelines for making a determination of whether or not the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” have been used.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims: The instant claims encompass many compounds ranging from an aromatic carbocyclic moiety to an aromatic carbocyclic moiety having many large electron withdrawing and bulky groups substituted on it to a moiety having many heterocyclic rings having many large and various groups hanging from it. These compounds cover a very wide range of compounds with the probabilities of the the Rx, Ry, Rz, Rf substitutions.

The nature of the invention: The invention is a (highly) very specific since it is used to treat diseases, since compounds work in a lock and key mechanism and that is useful as pharmaceuticals..

The state of the prior art: The WO 99/32437 patent teaches similar compounds with pharmaceutical uses . With only two substituents the amino and nitro.

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The level of one of ordinary skill: The ordinary artisan is highly skilled.

The level of predictability in the art: It is unknown what the level of predictability is in the art since the working examples either in the specification or in the prior art of compounds doing similar activity have only limited type of substituents.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: Since there are working examples only with respect to one the substituents - CON Ra Rb, the amount of experimentation is very high and burdensome and the few compounds made do not represent the fullest extent of the instant claim 1.

Taking the above factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and use the full scope of the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9932437 Oremus Vladimir et al .

Scope and Content of the Prior Art.

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Oremus '427 discloses the compounds similar to those of the claimed invention. See abstract and the whole document, wherein X is an Oxygen, R1 is an aryl (pyridyl example 23-25, 51) . These compounds read on the claims of the instant application when A is L-M-L' when L is a phenyl, m is Oxygen, L' is a phenyl ; B is a pyridyl.

Difference between the Prior Art and Claims.

The difference is in one of the substituents on L'.

The prior art suggests that it is a nitro or an amino group and the instant claim on the L' variable suggest that it be a SO₂ Rx, CORx or CN(Ry)Rz.

Prima Facie Obviousness and Motivation.

One of skill in the art would have been motivated to make a substitution similar to a nitro or amino group such as CN(Ry)Rz and CORx which differs by just one carbon atom.

The specifications do not have any side by side comparison between the closest prior art and the compounds with this variable substituent.

Applicant is required to provide a sided by side comparison of the unexpected results between the closest prior art and the instant claims.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Desai whose telephone number is (703) -305-1868. The examiner can normally be reached on Monday to Friday from 8.00 am to 4.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner , Mr. Alan Rotman, can be reached on (703) 308-4698.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235 .

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R.D.

Dec. 27th 2001.

A handwritten signature in cursive script that reads "Alan L. Rotman".

ALAN L. ROTMAN
PRIMARY EXAMINER